REMARKS

Claims 1, 3, 5-7, 10-19 and 21 are pending in this application. No claim has been added, deleted or amended herein. Accordingly, upon consideration of this Response, claims 1, 3, 5-7, 10-19 and 21 will still be pending and under examination.

35 U.S.C. §103

The Examiner rejected all pending claims under 35 U.S.C. §103 as allegedly obvious over U.S. Patent No. 6,303,141 (US '141), in view of EP 349 430 (EP '430) and Roark, et al.

Applicants respectfully traverse this rejection.

The claimed invention provides a matrix-controlled transdermal therapeutic system. This system comprises (i) an active ingredient-impermeable cover layer, (ii) a self-adhesive matrix layer, or a plurality of matrix layers of which at least the matrix layer exposed while applying the system is self adhesive, or one or more matrix layers whose surface remote from the cover layer and intended for adhesion at the application site is coated with an adhesive, the matrix layer(s) comprising at least one ACE inhibitor (angiotensin converting enzyme inhibitor) selected from the group consisting of imidapril, fosinopril, moexipril, perindopril, ramipril, spirapril, cilazapril, benazepril and trandolapril, *wherein the inhibitor is in the form of a dicarboxylic acid which is derivatised to form a diester*, and (iii) a removable protective layer.

In the Office Action, the rejection appears to be based on the incorrect understanding that monosalts are still within the scope of the claims. Specifically, on page 4, lines 1 and 2 of the Office Action, the Examiner states that although US '141 teaches active salts and acid of ACE inhibitors, it does not specifically teach monosalts as claimed by claim 1.

Applicants again note that the inhibitor in the claimed system is an ACE inhibitor in the form of a dicarboxylic acid that is derivatised to form a diester, but *not a monosalt*. Notably, active salts are no longer encompassed in the claimed system.

The Examiner fails to present a proper rationale as to why the claimed invention "as a whole" would have been obvious to a skilled artisan as of the filing date. Specifically, none of US '141, EP '430 and Roark et al. teaches or suggests a dicarboxylic acid diester derivative of an ACE inhibitor, let alone diesters of the claimed ACE inhibitors. In fact, as admitted in previous actions, US '141 is entirely silent about diesters of ACE inhibitors. Similarly, EP '430 does not teach or suggest any diesters of ACE inhibitors, and instead, discloses ACE inhibitors in their active dicarboxylic acid form or in a salt form.

There is also no teaching by Roark, et al. of any dicarboxylic acid diester derivatives of ACE inhibitors. Specifically, Roark et al. disclose monoacids and diacids of modified peptide inhibitors of angiotensin-converting enzyme (page 2292, Table I of Roark, et al., especially column R and column AA-OH). Moreover, Roark, et al. teaches that the diacids were more potent than the monoacids (page 1293, left column, penultimate paragraph).

In sum, the cited references, when combined, fail to teach all elements of the invention.

Nevertheless, the Examiner asserts that it would have been obvious to take a transdermal system for delivering salts of ACE inhibitors as disclosed by US '14l, and replace such salts with dicarboxylate derivatives of ACE inhibitors taught by EP '430, because EP '430 teaches that dicarboxylate derivatives of ACE inhibitors show improved flux through the skin. The Examiner also asserts that it would have been obvious to replace the dicarboxylate derivative of an ACE inhibitor with a diester derivative of a dicarboxylic acid form of an ACE inhibitor as allegedly taught by Roark, et al., because Roark, et al. allegedly teach that diester derivatives of dicarboxylic acid forms of ACE inhibitors are very potent antihypertensive drugs (see Office Action, at the paragraph bridging pages 4 and 5).

The Examiner's conclusion, however, is not supported by the cited references. Again, Roark, et al. does not teach or suggest an ACE inhibitor in the form of a dicarboxylic acid that is derivatised to form a diester. Consequently, this reference, in combination with the others, fails to provide any basis for the claimed diester derivatives of ACE inhibitors. It exhausts credulity to conclude otherwise.

In view of the above, applicants maintain that the cited references fail to create a reasonable expectation of success regarding the unexpected properties of the claimed system, particularly given that all the cited references fail to teach a dicarboxylic acid diester derivative of an ACE inhibitor.

For the above reasons, applicants maintain that the claimed invention is not obvious.

Conclusion

This application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

If any additional fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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Dated: December 23, 2009